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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,489	10/08/2003	Anita Maria Burgher	AM100459	5899

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EXAMINER	
BARHAM, BETHANY P	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/681,489	BURGHER ET AL.	
	Examiner	Art Unit	
	Bethany P. Barham	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/08/2003, 03/18/2004,and 09/21/2005.

DETAILED ACTION

Receipt is acknowledged of the Information Disclosure Statements filed on 10/8/2003, 3/18/2004 and 9/21/2005. Claims 1-7 are pending. Claims 1-7 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Gil et al US 5,066,500.

Gil et al teach the limitations of claims 1-3:

- The infant formula of Gil et al teaches that the terms uridine phosphate, guanosine phosphate, etc is intended to refer collectively to mono, di and/or tri phosphates but that for reasons known to those skilled in the art, the 5'-monophosphates are preferred (col 5, lines 8-13). Gil et al teaches an infant formula adding on a liquid basis, per dl, 0.28-2.62 mg of uridine phosphate, 0.04-

0.5 mg of guanosine phosphate, 0.64-1.43 mg of adenosine phosphate, 0.53-1.53 of cytidine phosphate and 0-0.29 mg of inosine phosphate (col 5, line 66-col 6 line 5; and claim 12). The supplementation of nucleotides to infant formulas of Gil et al gives a better physiological fatty acid tissue membrane to newborns, an improved cell immunity and better intestinal repair to those patients with intestinal diseases (col 5, lines 14-20).

Gil et al teach the limitations of claims 4-6:

- Gil et al teaches a diet formulation containing 0.2-60 mg/dl each on a liquid basis of nucleotides (a-e) uridine phosphate, guanosine phosphate, adenosine phosphate, cytidine phosphate and inosine phosphate (col. 5, lines 35-42). Gil et al teaches a preterm infant formula (Example I, Table IV) containing 11.8 mg/L total concentration of nucleotides, and other infant formulas (Examples II-VI) contain 10-13-21.4 mg/L total concentration of nucleotides (a-e).

Gil et al teach the limitations of claim 7:

- Gil et al teach infant formulas and nutrition products enriched with nucleosides, nucleotides and mixtures thereof to be fed to low birth weight newborns or term healthy infants (col. 1, lines 13-27). Gil et al teach that these infant formulas are adequate to meet the needs of preterm or low birth weight infants (Example 1 and Table IV) and then teaches varying the amounts of nucleotides in the infant formula to meet the needs of term healthy infants, lactose intolerant infants, or infants who need a hypoallergenic formula (col 6, lines 31-40; See Examples II-VI).

The teachings of Gil et al are discussed above and anticipate the instant claims. Gil et al teaches infant formulas, including preterm infant formulas. The nucleotide ranges claimed by applicant in the instant application overlap with the ranges of CMP, AMP, UMP, and GMP as claimed in claim 12 of Gil et al, while the range for IMP as claimed by applicant is contained within the range claimed by Gil et al. Gil et al also teaches total nucleotide concentrations for infant formulas and adult nutritional diet products from 10-3000 mg/L, but teaches examples specific to infant formulas in the range of 10.13-21.4 mg/L (Examples I-VI). Gil et al teaches administering the claimed infant formulas orally or by enteral feeding tubes to low birth weight or preterm infants in order to stimulate repair and regeneration of intestinal gut cells, enhance the immune response of T-cells and provide for specific fatty acid phospholipids profiles in red blood cell (col 1, lines 13-25 and col 6, lines 35-40).

Claims 4-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuhlmann et al US provisional application 60/343,253 (now US patent 6,913,778 B2).
Kuhlmann et al teach the limitations of claims 4-6:

- Kuhlmann et al teaches in example 2 an infant formula having a total nucleotide concentration of 29.5 mg/L.

The teachings of Kuhlmann et al are discussed above and meet the limitations of the claims. The MPEP 2131.03 states that "[W]hen, as by a recitation of ranges or

otherwise, a claim covers several compositions, the claim is anticipated' if one of them is in the prior art." So the range of compositions claimed by applicant in the instant invention is anticipated by the single composition of Kuhlmann et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhlmann et al US provisional application 60/343,253 (now US patent 6,913,778 B2).

Kuhlmann et al teach the limitations of claim 1:

- Kuhlmann et al teaches an infant formula containing nucleotides CMP, AMP, GMP, UMP, and IMP (pg. 5 lines 7-8, Example 2). Kuhlmann et al teaches in

example 2 an infant formula (control and invention) containing 16.5 mg/L of CMP; 5.0 mg/L of UMP; 4.0 mg/L of AMP; 2.0 mg/L of GMP and 2.0 mg/L of IMP (p.16-17, Table7).

Kuhlmann et al teach the limitations of claim 7:

- Kuhlmann et al claims in claim 7: "a method of feeding an infant, comprising feeding a nutritionally sufficient amount of the infant formula of claim 1 to an infant less than one year of age."
- Kuhlmann et al does not teach CMP within the range 3.2-15.4 mg/L as claimed by applicant, but does teach the formula containing 16.5 mg/L of CMP.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Kuhlmann et al for how to include the nucleotides CMP, AMP, UMP, GMP and IMP in infant formula for feeding of infants of any kind. One of ordinary skill in the art would be motivated to look to Kuhlmann et al in order to make an infant formula containing nucleotides and optimize the concentrations of nucleotides to obtain workable ranges. The MPEP 2144.05 states: *"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."* Thus, it would have been *prima facie* obvious at the time the invention was made to look to the infant formula of Kuhlmann et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany P. Barham whose telephone number is 571-272-6175. The examiner can normally be reached on M-F from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B.P. Barham
Examiner 1615

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